**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL No. 1456<br><br>CIVIL ACTION: 01-CV-12257-PBS |
| THIS DOCUMENT RELATES TO: *State of Iowa v. Abbott Laboratories., et. al.* | Judge Patti B. Saris |

**DEFENDANT ENDO PHARMACEUTICALS INC.'S INDIVIDUAL MOTION TO DISMISS THE COMPLAINT OF THE STATE OF IOWA AND MEMORANDUM OF LAW IN SUPPORT THEREOF**

Pursuant to this Court's December 18, 2007 Order, Defendant Endo Pharmaceuticals Inc. ("Endo") hereby moves this Court to dismiss the Complaint of the State of Iowa and submits this memorandum of law in support thereof.

## I. PLAINTIFF'S FUL FRAUD ALLEGATIONS SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM

### A. Plaintiff's FUL Fraud Allegations

Plaintiff alleges that Endo and numerous other defendants engaged in FUL[1] fraud. In support of its theory, Plaintiff alleges generally: (1) the manner in which the federal government calculates FULs pursuant to 42 C.F.R. § 447.332, Complaint at ¶ 102; (2) that Endo failed to submit accurate pricing data to the publishing compendia; (3) that, "in many instances, had [Endo] submitted accurate prices to pricing compendia, the FULs set by CMS would have been lower and the Iowa Medicaid Program would have paid less," Complaint at ¶ 104; and (4) that

[1] FUL, or federal upper limit, is established by the federal government, and is a payment level set at 150% of the published price for the least costly therapeutic equivalent of a multiple source drug that can be purchased in quantities of 100 tablet or capsules, or if not commonly available in that quantity, the package size or liquid volume commonly listed. *See* 42 C.F.R. § 447.332.

Endo was aware of "the reimbursement prices reported by [its] competitors, the actual price of [its] generic competitors' products, [its] own sale prices to Medicaid providers and the FUL," Complaint at ¶ 106. In Exhibit B to the Complaint, Plaintiff sets forth the specific Endo NDCs for which it alleges FUL fraud. Plaintiff alleges that, for the NDCs identified in Exhibit B, Endo's "true price . . . was more than 50% lower than the established FUL." Complaint at ¶ 108, *see* Complaint at ¶ 367. Plaintiff alleges that for those NDCs, because the allegedly true price was more than 50% lower than the established FUL, "Endo's failure to report accurate prices for the above drugs and those set forth in Exhibit B-13 resulted in false and inflated FULs being issued, and overcharges to Iowa Medicaid directly attributable to Endo." Complaint at ¶ 368, *see* Complaint at ¶ 108.

**B. Plaintiff Fails To Allege Adequately The Elements Of FUL Fraud Against Endo**

The Complaint should be dismissed for failure to state a claim, because the Complaint fails to set forth the requisite "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." *Centro Médico del Turabo, Inc. v. Feliciano de Melecio*, 406 F.3d 1, 6 (1st Cir. 2005) (*quoting Berner v. Delahanty*, 129 F.3d 20, 25 (1st Cir.1997)); *Roth v. United States*, 952 F.2d 611, 613 (1st Cir. 1991); *Gooley v. Mobil Oil Corp.*, 851 F.2d 513, 515 (1st Cir. 1988).

In particular, while Plaintiff alleges that the actual prices for Endo's NDCs were more than 50% lower than the FUL, nowhere does the Complaint "make factual allegations" concerning the key "material element necessary to sustain recovery," namely that the price set for any given Endo NDC was eligible to affect the FUL calculation under the methodology for setting the FUL described in the Complaint. Under that methodology, any given Endo drug listed in the Complaint could not – as a matter of law – "result in a … FUL being set" unless 1)

the Endo drug has "been evaluated as therapeutically equivalent,"[2] and (2) the Endo drug "can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size most commonly listed), or in the case of liquids, the commonly listed size."[3]

Plaintiff must therefore "make factual allegations … respecting these material elements" of its legal theory. That is, Plaintiff must allege that the listed Endo NDCs meet the two criteria – therapeutic equivalence and quantity – necessary to establish that those NDCs in some way affected the FUL set for those drugs. Absent adequate factual allegations that the Endo NDCs were legally eligible to affect the FUL, the Complaint is not sufficient to state a claim under the Plaintiff's own legal theory that the pricing of a given Endo NDC "resulted in a false and inflated FUL being set." Because Plaintiff fails to allege as to any given Endo drug that the drug is a therapeutic equivalent or that the drug was sold in the quantities required for that drug to be eligible to set the FUL, the Complaint should be dismissed as to all Endo drugs subject to a FUL.

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[2] 42 C.F.R. § 447.332(a)(1)(i) (defining the drugs eligible for use in calculation of the FUL as "therapeutically equivalent in the most current edition of [the FDA] publication, Approved Drug Products with Therapeutic Equivalence Evaluations [also known as the Orange Book] (including supplements or in successor publications)." S*ee also* Complaint at ¶102 (*citing* 42 C.F.R. § 447.332). The Orange Book provides additional information regarding the definition of therapeutically equivalent drugs. *See* Orange Book, Introduction and Sample Page 3-1, attached as Exhibit 1 (available at: http://www.fda.gov/cder/orange/obannual.pdf).

[3] 42 C.F.R. § 447.332(b); *see also* Complaint at ¶102 (*citing* 42 C.F.R. § 447.332). *See also generally*, CMS Transmittal No. 37 – Federal Upper Limit Drug List, at 1 (Nov. 20, 2001), attached as Exhibit 2 (listing drugs that meet the criteria set forth in 42 C.F.R. § 447.332, determined by applying 150% "to the lowest price listed (in package sizes of 100 units, unless otherwise noted) in any of the published compendia of cost information of drugs.")

## II. PLAINTIFF FAILS TO ALLEGE ANY SPECIFIC MISREPRESENTATIONS MADE BY ENDO

Plaintiff fails to allege any specific misrepresentations made by Endo, and therefore fails to plead fraud with the specificity required by Rule 9(b) of the Federal Rules of Civil Procedure.

Plaintiff alleges that Endo engaged in AWP fraud. Complaint at ¶ 361. However, the Complaint does not contain a single allegation that Endo ever reported a false *AWP*. Rather, Plaintiff contends that "Endo reports false and misleading *WACs* in order to inflate the published AWPs for its products and enable Endo to create a spread." Complaint at ¶ 363 (emphasis added). The Complaint purports to set forth AWPs for Endo products published by the price reporting services in ostensible reliance on the WAC information allegedly provided by Endo, *see* Complaint ¶ 364, but nowhere does the Complaint specify any allegedly false WAC prices that Endo allegedly provided to the third party price reporting services. Nor does the Complaint identify any relationship between the WACs Endo allegedly reported and the AWPs ultimately published by the price reporting services. The Complaint alleges that "AWPs are *often* set pursuant to a standard formula and based on the reported WAC" and the mark-up formula has a "*typical* range" of 20-25%. S*ee* Complaint ¶¶ 91, 95 (emphasis added). However, the Complaint fails to allege (1) whether this standard markup was applied to Endo's reports of WAC information, (2) if so, what the mark-up percentage was (20% or 25%), and (3) what purportedly false WACs were reported by Endo that "caused" any inflated AWPs to be reported.

Accordingly, Plaintiff's claims fail to allege the "time, place, and content of the alleged false or fraudulent representations" required by Rule 9(b). *See U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 226 (1st Cir. 2004); *Massachusetts v. Mylan Labs.*, Civ. Action No. 03-11865-PBS, Mem. at 2 (D. Mass. Apr. 5, 2005) (finding complaint asserting WAC pricing fraud claims insufficient to meet the requirements of Rule 9(b) where the plaintiff failed

to "state whether AWP or WAC was communicated for each drug, and to whom it was communicated," and failed to provide "details about how or by whom the allegedly fraudulent WACs were calculated if the Defendant did not state WACs"). If Plaintiff contends Endo reported false WACs, it must identify the specific reports of WAC information purportedly made by Endo and it must state how and by whom the allegedly fraudulent AWPs were calculated. *Id.*

This deficiency is unique to Endo. With respect to every other defendant alleged to have reported false and misleading WACs, Plaintiff identified at least one allegedly false WAC or AWP reported by that defendant, but failed to do so as to Endo. Because Plaintiff has not alleged any "false and misleading" statements purportedly made by Endo, Plaintiff has not adequately alleged the "content" of the alleged false or fraudulent representations as required by Rule 9(b) of the Federal Rules of Civil Procedure. The Complaint should therefore be dismissed as to Endo.

**CONCLUSION**

For the reasons stated above and in the Memorandum of Law in Support of Certain Defendants' Motion to Dismiss the Complaint, the Complaint should be dismissed as to Endo.

Dated: February 20, 2008
Washington, DC.

Respectfully submitted,

ARNOLD & PORTER LLP

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*Counsel for Defendant Endo Pharmaceuticals Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on February 20, 2008, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ David D. Fauvre